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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,965	11/14/2003	Charles H. Pugsley	06530.0288-01	7789
22852	7590	01/03/2007	EXAMINER	
FINNEMAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413			KOHARSKI, CHRISTOPHER	
		ART UNIT		PAPER NUMBER
				3763
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/706,965	PUGSLEY ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christopher D. Koharski	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 October 2006.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-2, 6-9 and 11-46 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 25-30, 32, 33, 35 and 36 is/are allowed.  
 6) Claim(s) 1, 2, 6-9, 11-24, 31, 34 and 37-46 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_.  
 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Response to Amendment***

Examiner acknowledges Applicant's reply filed 10/30/2006 with claims 1, 2, 6 and amended and new claims 37-46 added and claims 3-5 and 10 cancelled. Currently claims 1-2, 6-9, and 11-46 are pending for examination.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 10/30/2006, with respect to the rejection(s) of claim(s) 1-2, 6-9 and 11-46 under the prior have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see below).

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2, 6-9, 11-24, 31, 34 and 45-46 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Regarding claims 1-2, 6-9, 11-24, 31, 34 and 45-46, the scope of Applicant's specification in defines the *tissue sheet* as a *suspension of cells* or *genetically engineered tissue* construct, which is in line with being constructed of living matter as the definition above clearly states below is not patentable.

The term "tissue" is defined as:

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Noun. an aggregate of similar cells and cell products forming a definite kind of structural material with a specific function, in a multicellular organism.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Nuwayser (4,687,481). Nuwayser discloses a transdermal drug delivery system.

Regarding claims 37-42, Nuwayser discloses a tissue patch comprising a substrate (12) having a first and second surface and therapeutic agent (18,20), a tissue implant (14) attached to the first surface occupying a first area of the first surface of the substrate, a removably protective liner (24) attached to the first surface to cover the tissue implant, and an adhesive (22) that occupies a second surface than that of the tissue implant (14) which is defined as the outer edge of the first surface of the substrate and is configured to hold the patch to a lesion surface (col 1, ln 1-60, Figures 1-2). The trans-dermal patch is capable of being folded and unfolded to aid in its positioning (Figures 1-2).

***Allowable Subject Matter***

Claims 25-30, 32-33 and 35-36 are allowed.

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***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Houser et al. (6,149,681).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/18/06



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